LABORATORY TERRORISM PREPAREDNESS NEWSLETTER

Maryland Department of Health and Mental Hygiene
Laboratories Administration

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Unknown Powders/Liquids

Effective April 1, 2004, the Laboratories Administration will begin accepting unknown powders and liquids that law enforcement believes to be associated with credible threats to public health. Although analysis by Fourier Transform Infrared (FTIR) spectrometry can often provide identification within 30 minutes, unknown samples must first be tested for contamination by bioterrorism (BT) agents, such as anthrax. This will normally delay obtaining identification for 24-48 hours after the State Lab receives the sample.

This new service is being introduced to further support Maryland's law enforcement, public health, and environmental agencies. Until now law enforcement and other agencies that needed powders identified first had to submit them to the State Laboratory for BT agent testing. Then, once the sample was found negative for a BT agent, the agency had to again pick up and transport the sample to a second laboratory. This was not only inefficient but also subjected the courier and the environment to potential contamination. It also subjected the sample to potential damage and an extended chain of custody.

Remember that samples collected primarily as evidence in criminal cases (e.g., suspected controlled dangerous substances) should <u>not</u> be submitted to the Laboratories Administration. These should continue to go to one of the State's police crime laboratories.

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Law enforcement, hazmat, and fire departments must also remember that any powder, to which a credible biological threat has been assigned, must first be tested for potential biological contamination. **If an agency has its own field-portable FTIR and suspects a sample may contain a possible pathogenic agent, the sample should be sent to the State lab and <u>not</u> tested in the field.** Otherwise field-testing could lead to potential contamination and infection of field staff and contamination of the FTIR and surrounding environment.

Furthermore, **FTIRs of the types in use are unable to detect substances in a mixture if those substances make up less than 5% of the mixture**. This would preclude detection of most potential BT agents because they would be expected to make up far less than 5% of the sample.

Recent Alerts Test MLRN

(1) Ricin Confirmation and Screening

At 2:45 a.m. on February 3, 2004, a call was taken from the FBI by the Laboratories Administration's Director of Laboratory Emergency Preparedness and Response and quickly relayed to the Director of the State Laboratory. By 5:00 a.m. the Chief of the Administration's Molecular Biology Division had received, from an FBI agent, four paperdust samples collected from an automated envelope opener in the Dirksen Senate Office Building in Washington, DC. These samples were immediately processed and tested for ricin by time-resolved fluorescence (TRF). Several of these samples had previously been found positive by another laboratory and were sent for confirmation to the Laboratories Administration by virtue of it being an approved Laboratory Response Network (LRN) Laboratory.

Around 10:30 that morning the Laboratories Administration participated in a CDC operations teleconference and learned that the State Lab would

receive from CDC, by courier flight, additional TRF test reagents and a new, non-validated PCR protocol to test for ricin. The Maryland State Public Health Laboratory is the first laboratory outside CDC to receive this new PCR. During that teleconference, the State Lab also learned that approximately 30 additional samples would be collected from a postal facility upstream from the Dirksen building and that those samples would be delivered to our lab around 5:00 p.m. that same day. The State Lab also participated at 3:00 p.m., on both February 3 and 4, in a DHMH-sponsored teleconference to brief and update county and local health departments on the ricin events.

At 11:30 a.m. on February 3 the Laboratories Administration reported to the FBI, CDC, and DHMH that 3 of the 4 samples delivered early that morning were positive for ricin. The postal facility samples, expected around 5:00 p.m., didn't arrive until 7:30 p.m., and the expected 30 samples proved to be 65 in number. This required that a team of employees be retained to work until 8:30 p.m. to process the samples so testing could begin early the next morning. The Division Chief, who had begun his day at 3:00 a.m., remained at the lab until midnight, when the CDC courier arrived with the awaited TRF reagents and the new PCR protocol.

Testing of 46 of the 65 postal facility samples was completed by noon on February 4. The remaining 19 were completed that same day by 4:00 p.m. All 65 samples were negative for ricin. This two-day-long "ricin" event proved to be an excellent test of the Laboratories Administration's 24/7 communication system, its emergency essential employee response, its analytical capabilities and expertise, and the effectiveness of communications between the State Lab and FBI, CDC, and DHMH.

(2) Mysterious Equine Death

At 10:30 p.m. on Sunday February 8, 2004, a veterinarian at one of the Maryland Department of Agriculture's (MDA) State Veterinary Diagnostic Labs informed the Laboratories Administration's Director of Laboratory Emergency Preparedness and Response that a horse had mysteriously died. Necropsy specimens from the animal had yielded a culture of organisms that appeared, using an API test strip, to test positive for *Yersinia pestis*, the cause of plague.

Because plague in a horse is extremely rare, the Laboratories Administration Director asked that the specimen be held until the next morning when it could be submitted to the State Lab for PCR testing. That morning the Chief of the Administration's Environmental Microbiology Division personally picked up the agar-plated culture from the veterinary lab and delivered it to the State Lab's Molecular Biology Division for PCR testing, and to the Public Health Microbiology Division for further bacterial culturing and testing. The Administration also kept in close contact with the Epidemiology and Disease Control Program's staff at DHMH who were briefing pertinent county health departments.

Around 4:00 p.m. that Monday the Laboratories Administration reported that the isolates were negative for *Y. pestis* by PCR. Additional testing by the Public Health Microbiology Division showed that the original isolation plate was also negative for anthrax but contained two different bacterial species, one that grew more slowly than the other. The more slowly growing colony would not easily have been seen on the original plate and probably resulted in inoculation of both species in the API strip, causing a false biochemical reading.

This pseudo-event served as another good exercise and test of the Maryland Laboratory Response Network's ability to respond quickly and effectively to the needs of its member laboratories. It also shows the importance of DHMH and MDA's partnership and close working relationships.

New Advisory Committee

In September 2003 the MLRN's Laboratory Terrorism Preparedness Advisory Committee held its first meeting. Its initial charge was to help coordinate the State Laboratory's training of sentinel laboratorians and first responders and to help develop and improve information and communication strategies among MLRN laboratories.

The Committee proved especially useful in helping the Laboratories Administration's Office of Laboratory Emergency Preparedness and Response prepare and distribute a 'look-alike' BT agent challenge set (see following article). The Committee is also preparing a list of materials and information that will be made available to first responders and LRN member labs on the Laboratories Administration's BT website. The Committee meets bimonthly and consists of the 18 officials and ex-officio members listed on page 3.

FERN

The Food Response Network (FERN) integrates the Nation's laboratory infrastructure to detect threat agents in food. FERN laboratories are responsible for the detection of biological, chemical and radiological agents in food. The Laboratories Administration is currently applying for membership in FERN as a reference laboratory that tests food for one or more of the above three types of agents.

The Laboratory Terrorism Preparedness Newsletter is published periodically by the Staff of the Office of Laboratory Emergency Preparedness and Response, Laboratories Administration, DHMH, 201 W. Preston St., Baltimore, MD 21201 (410-767-6082). We encourage all to submit, at any time, articles for this newsletter to the above office via FAX (410-333-5001). Questions concerning technical content of this newsletter may be referred to Ross Brechner, MD, MS,.MPH, Director of that office.

Lab Terrorism Advisory Committee Members		
First Name	Last Name	Org Name
Lane	Ahlburn	DHMH Labs Admin
Ed	Bonner	Harford Memorial Hospital
Ross	Brechner	DHMH Labs Admin
Michael	Deabay	Southern Maryland Hosp Ctr
Mitchell	Dinterman	Maryland State Police
Joseph	Haney	DHMH Labs Admin
Phyllis	Cassano	MDA
Prince*	Kassim	DHMH Labs Admin
Julia *	Kiehlbauch	DHMH Labs Admin
Helen	McQuay	Shore Health
Robert *	Myers	DHMH Labs Admin
Polly	Ristaino	St. Joseph Med Center
Jeffrey	Roche	DHMH Epi and Disease Control
Michael	Sharon	MDE
Jim	Svrjcek	DHMH Labs Admin
Art	Thacher	DHMH Info Resources and Management Divsion
Kenneth*	Wilde	DHMH Labs Admin
Gail	Wowk	DHMH Public Health Svcs

*= ex-officio

Challenge Sets

The team of sentinel laboratories in Maryland, known as the Maryland Laboratory Response Network (MLRN), is continually undergoing training as part of Maryland's preparations to respond to a terrorism event. As part of that effort the Laboratories Administration's Office of Laboratory Emergency Preparedness and Response recently prepared and distributed sets of three lyophilized, microorganisms that had certain characteristics similar to several BT agents. This initial 'look-alike' BT agent challenge set was prepared for distribution on a voluntary basis to the State's sentinel labs. The vials were hand-carried to participating laboratories. These visits took a full week to complete and, in addition to ensuring safe and efficient transport of the challenge set, they allowed staff in the Office of Laboratory Emergency Preparedness and Response to meet the sentinel lab personnel throughout Maryland and visit their laboratories.

That Office has since received test results from all the 53 of the 60 labs that were able to participate. The MLRN is proud to say that just about all of the laboratories were able to identify the unknowns. Currently we are drawing up a letter of thanks to all the laboratories and plan to repeat this exercise about once a year. So, thanks to all for your support, help, and participation in this important exercise. It went a long way in proving the analytical capability of the MLRN's sentinel laboratories.

BPARA of 2002

On June 12, 2002, a new federal law went into effect that will permanently influence everyday laboratory life, as well as all of public health. It is known as the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (BPARA). Title II of the Act deals with "Enhancing Controls on Dangerous Biological Agents and Toxins." These agents and toxins are also known as Select Agents and Toxins (SA&T). This Act and those agents are the focus of this article. The purpose of the Act is to improve response to public health emergencies. A definition of Select Agent is as follows:

> *Select agent or toxin* or *select agent and toxin without identification*, means all of those biological agents or toxins included in §§ 73.4 and 73.5 of 42CFR73 (the portion of the Code of Federal Regulations that pertains to BPARA).

A list of these SA&T, along with the criteria for creation and biennial review of this list are included in the Act. Keep in mind that this list is in constant flux, because CDC is continually evaluating organisms for exclusion from the main list. You can keep up with these changes by following them on the following website; http://www.cdc.gov/od/sap/exclusion.htm.

General Prohibitions of the Act are stated with respect to the possession or use of Select Agents for lawful purposes. As expected, these prohibitions deal mostly with research, diagnosis, and treatment as well as manufacture and transport. One interesting aspect of BPARA is that it separates agents into three categories:

1. Those that relate to human pathology only and are controlled by HHS;
2. Those that are related to animal and plant toxin pathology only and are controlled by USDA; and
3. Those that are related to both human and animal pathology and are considered "overlap" agents, those regulated by both USDA and HHS.

If your facility possesses, maintains or transfers Select Agents it must undergo federal facility registration and meet all requirements. For example, spill procedures and equipment must be present in all rooms. Eyewash stations are expected to be within required distances. Everyone who enters and exits rooms where Select Agents are stored or used must record each entrance and exit. In addition, all handling of Select Agents must be carefully recorded and agent-specific and room-specific biosafety manuals and emergency plans must be easily accessible in the appropriate rooms.

Exemptions or exclusions of a facility for any agents or for specific agents are as follows:

1. **The facility is a clinical lab checking specimens for diagnosis only, and if a Select Agent is found it is promptly reported to the proper agency and destroyed. (The Select Agent may not be retained as a reference or control).**
2. The agent has an FDA approval (e.g., BOTOX).
3. There is a public health emergency.
4. The Select Agent is from its natural environment.
5. The Select Agent is nonviable.
6. The Select Agent is non-functional, as in toxins.
7. The Select Agent is present in a permitted amount (i.e., toxins per Principal Investigator are in amounts less than maximum amounts set in BPARA).
8. The agent is not on the Select Agent list at all, or is on the Select Agent list as an exclusion (e.g., *Bacillus anthracis* Sterne strain). Exclusions also may be found at the website listed above.

Another key issue with respect to registration is that BPARA stipulates that **"restricted persons"** are not permitted to handle Select Agents in your facility. The definition of a "restricted person" is one that falls under any of the following categories:

1. Person has a criminal conviction.
2. Person is a fugitive from justice.
3. Person is an unlawful user of drugs.
4. Person is an illegal alien.
5. Person has a mental deficiency.
6. Person is a member of a terrorist organization.
7. Person is a member of an organization tied to violence.
8. Person is an agent of a foreign power.

The Act covers numerous additional topics. Security and Safety procedures are facility dependent, but each facility is encouraged to adapt their own general security rules. Laboratories should carefully review the *Biosafety in Microbiological and Biomedical Laboratories 4th Edition* using it as "the" reference for biosafety and security.

Another important topic in the Act is the assignment of a facility "Responsible Official" (RO) and alternate (ARO). The RO and ARO are responsible for ensuring compliance. The law suggests that the RO be either a member of senior management or a biosafety official, preferably someone that doesn't work directly with Select Agents. BPARA spells out the duties of the RO and they include:

1. Developing and implementing a safety, security and emergency response plan;
2. Controlling access to Select Agents;
3. Providing training to persons regarding safety, security and use of Select Agents, and making sure they are trained at the time they start work with Select Agents;
4. Transfer of Select Agents;
5. Timely reporting of theft, loss, or release of Select Agents to HHS;
6. Maintaining records of many types including the facility inventory of Select Agents;
7. Timely reporting of Select Agents and Toxins identified in the facility during diagnosis;
8. Vouching for all the above.

A section of the law deals with the tricky issue of tracking the transfer of select agents between facilities. A few important instructions must be followed. First, the federal form EA101 must be filled out by each facility. Second, both facilities must be registered for the Select Agent to be transferred. Third, the Principal Investigator for that agent, in both the sending and receiving facility, must sign the EA101, as must the RO. This must be done in advance of the transfer. If the shipment does not arrive on time, or if there is damage to the package, the HHS must be notified.

The Act goes on to provide references for emergency response plans and training guidelines, state that facility inspections may be made by HHS at any time, and require that accurate and complete record keeping is paramount. The remainder of the Act deals with administrative review, civil penalties (considerable and in the range of $250,000), criminal penalties, and contact information for submissions and forms.

The take home message is that even though your facility (e.g., a clinical laboratory) may not need to be registered under BPARA, you and your facility may suddenly be put in a position of needing to comply with BPARA. Therefore familiarization with this law is very important. The Federal Government is taking this law and its enforcement very seriously.

24/7 Emergency Contact Numbers

TERRORISM EMERGENCY PREPAREDNESS PHONE NUMBERS	
Sample/Specimen Submission	
AFTER HOURS (Dial In Order)	**M-F 8:00AM-4:30PM**
410-471-0595 pager 1	**410-767-6085 phone**
410-925-3121 cell	**410-925-3121 cell**
410-869-0999 home	**410-471-0595 pager**
410-408-7521 pager 2	